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TOWNSEND and TOWNSEND and CREW LLP

By: _____

Lois M. Simón

PATENT

Docket No.: 02558B-063100US

Client Ref. No.: BRP00064

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michael I. Watkins et al.

Application No.: 09/548,883

Filed: April 13, 2000

For: MULTI-ANALYTE DIAGNOSTIC
TEST FOR THYROID DISORDERS

Examiner: Gabel, G.

Art Unit: 1641

REQUEST FOR CONTINUED
EXAMINATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request continued examination of this Application.

Submitted herewith are a Supplemental Information Disclosure Statement and the following comments.

The Supplemental Information Disclosure Statement includes two documents that are based on the Chandler et al. U.S. patent 5,981,180 submitted previously, and that contain additional disclosure of the use of the system described in that patent. They are submitted for completeness of the record, but are not considered to affect patentability of the current claims.

In the Office Action dated July 24, 2003, claims were rejected over combinations of Watkins et al. U.S. patent 6,280,618 with other references. Applicants had stated that at the time this invention was made, it and the Watkins et al. patent were owned by or subject to an assignment to the same assignee, namely the present assignee Bio-Rad Laboratories, Inc. In the Office Action, Examiner Nguyen stated that nevertheless the Watkins et al. U.S. patent was properly considered prior art

Applicants thank Examiner Nguyen for the telephone interview of September 8, in which this rejection was discussed. At that time Examiner Nguyen agreed that the Watkins et al. patent was not prior art in view of the above statement by Applicants, and agreed to withdraw the rejection.

Applicants would appreciate receiving a copy of the Examiner's Interview Summary and confirmation that this rejection has been withdrawn.

Subsequent to that interview, it was noticed that a published PCT application corresponding to the Watkins patent existed, with an earlier publication date, which is prior to this application's filing date. This is WO 99/26067, published May 27, 1999, and is also submitted in the accompanying Supplemental Information Disclosure Statement.

For the reasons stated below, Applicants submit that this publication, alone or in combination with the cited secondary references, does not render the current claims obvious.

In addition, Applicants believe that this reference is not a proper reference, as it in fact relates to work of inventors named or to be named in this Application. It thus does not represent work of another under 35 U.S.C. 102(a).

On this point, the inventorship of this Application includes Michael I. Watkins, who is one of the inventors in WO 99/26067. The other inventor named in that publication is Richard B. Edwards. He is not named as an inventor of this application; however, it is believed that he should have been so named. Documents to change the inventorship of this Application to include Dr. Edwards are being circulated; however,

they have not been fully executed at this time. Applicants plan to file them when they have been completed.

In any event, as discussed previously, Applicants do not consider the disclosure in WO 99/26067 (which is the same as in the '618 patent) to provide a basis for an obviousness rejection of the claims currently under examination.

WO 99/26067, like the '618 patent, is directed to general methods and techniques for conducting multi-analyte detection using differentiable particles. It contains much information about conducting multi-analyte testing using these systems. There are two specific mentions of multi-analyte techniques involving thyroid disorders. As the examiner notes, these are at p. 7 lines 20-21 and p. 8 line 15 (corresponding to col. 8 lines 54-55 and col. 9 lines 34-35 of the '618 patent). The first states that thyroid stimulating hormone (TSH) is an example of an analyte that can be detected using the techniques described in the reference. The second states that a combination of assays for TSH and either free T₄ or total T₄ can be conducted using the method of the reference.

The claims of this Application, on the other hand, describe a multi-stage process for conducting an assay for four or five different specific analytes using specifically coated particles, specifically defined labels and specific analytical techniques.

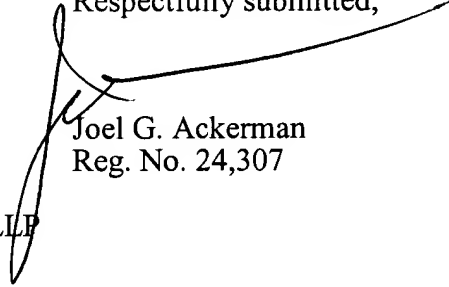
The examiner cites various secondary references. However, they do not provide information relating to the process as claimed. For example, Dietzen is directed to a providing a single liquid standard or calibration solution for use in a multi-analyte technique for assessing thyroid function, but describes very little about the multi-analytical technique itself. Smith et al. describes a dual-isotope technique using two of the thyroid components in what seems to be a competitive assay.

CONCLUSION

In view of the foregoing, Applicants believe the claims in this application are allowable, and request a Notice to that effect.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned.

Respectfully submitted,



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